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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,214	01/20/2006	Frank Pfluecker	MERCK3116	9757
23599 7590 06/25/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER NGUYEN, COLETTE B				
ART UNIT		PAPER NUMBER		
4162				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,214

Applicant(s)

PFLUECKER ET AL.

Examiner

COLETTE NGUYEN

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 1/20/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 13-21 drawn to a composition of a nano-particulate UV protectant and its final products thereof.

Group II, claim(s) 6-12, drawn to the process of making the said UV protectant.

Group III, claims 22-27 drawn to the method of using the said UV protectant.

1. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature does not provide a contribution over the prior art as the limitations of claim 1 are disclosed by the reference Schumacher et al(6,773,814). Since the special technical feature is disclosed by the prior art, that special technical feature does not provide a contribution over the prior art. Further, because PCT Rule 13. 2 states that a lack of unity exists when the special technical feature does not provide a contribution over the prior art, and because the examiner has disclosed references which teach this

special technical feature, a proper assertion has been made that there exists lack of unity.

2. During a telephone conversation with Mr. Brian Heaney from the attorney office on June 9th, 2008, a provisional election was made **with traverse** to prosecute the invention of Group I, claims 1-5 and 13-21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product, process and method of use claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process and method of use claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process and method of use invention must require all the limitations of an allowable product claim for that process and method of use invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process and method of use claims may be maintained. Withdrawn process and method of use claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.1-5, 13-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-12 and 22-27 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,4,5,14,16,17,18,20,21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Regarding claim 3. There is insufficient antecedent basis for " the crystallite size" in line 2. Also, there are more than one range is claimed, which renders the claim indefinite. The word "preferably" is considered indefinite. The metes and bounds of the claim are not clearly defined.
6. Regarding claims 4 and 5. There is more than one range and the word "preferably" are considered indefinite. The metes and bounds of the claim are not clearly defined.
7. Regarding claim 14. The word "preferably" is considered indefinite-. Doe the claim limit to a cosmetic or dermatological formulation? The metes and bounds of the claim are not clearly defined.
8. Regarding claim 16. "preferably" (same as above), and "in particular", also, "and/or" render the claim indefinite: Is the "and/or" in relation to the UV filter, or to the dibenzoylmethane derivative?
9. Regarding claims 17,18,19, "preferably" renders the claim indefinite and the metes and bounds of the claim are not clearly defined.
10. Regarding claim 20. "the protection of body cells" lacks antecedent basis".
11. Regarding claim 21. line 2, it is not clear what "it" is referring to; and "preferably" is indefinite.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 to 5, 13 to 16, 18 to 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher et al(US2003/0104198) . Schumacher et al. teaches a metal oxide particles coated with silicon dioxide, in particularly the titanium oxide, widely used in sun screening agent. The metal oxide is obtained by using hydrothermal process.

The teaching of the composition encompasses the composition of the instant claims.

3. **Regarding Claim 2.** Schumacher specifically teaches titanium oxide as the metal oxide. Doping with iron is optional therefore it is not required.(Col 3, line 7)

4. **Regarding Claim 3.** Schumacher teaches a coated metal oxide with dimension range of 2-100nm, preferably between 5-50 nm with a thickness of silicon dioxide of 0.5-25 nm of which the metal oxide has the dimension of 1.5-75 nm, comparing to 5-100nm as claimed. The dimensions of the metal oxide under a transmission electron microscope are inherent in the X- Ray diffraction range (Scherrer method is a X-Ray diffraction) of the crystal particle, therefore the dimensions of the particle in the instant

claim are already anticipated by Schumacher 's teaching for the metal oxide particle, especially the size range is overlapped. (Col2, line 51-55).

5. Regarding Claim 4. Schumacher teaches a thickness of silicon dioxide coating, expressed in nanometer of between 0.5 and 25 nm as compared to the metal oxide size of 2 to 100nm. In percentage, it is equivalent to 20%, based on the size of the metal oxide plus the thickness of the silicon dioxide. The claim is 12-20% by weight. The Schumacher teaching encompasses the thickness requirement of the silicon dioxide coating.(Col2,line 50-67).

6. Regarding Claim 5. Schumacher teaches a coated metal oxide particle with a dimension range of 2-100nm, preferably between 5-50nm. The dimensions of the coated metal oxide under a transmission electron microscope are inherent in the X- Ray diffraction range (Scherrer method is a X-Ray diffraction) of the particle, therefore the dimensions of the particle in the instant claim are already anticipated by Schumacher 's teaching for the coated metal oxide particle (Col 2, line 51-55)

7. Regarding claims 13,14,15. Schumacher teachings encompass the instant claims by specifically mentioning the applications of the silica-coated metal oxide powder not only in cosmetics but also widely to known inorganic UV-absorbing pigments used in industries. Sun screening (light protection) in the form of lotions, creams, mousses, milk sprays (dermatological formulation) also can be applied.(Col4, line 17-20, Col 5, line 1-10).

8. Regarding claims 16, 19, 20. Schumacher teaches the application of the silica-coated metal oxide in sun screen agents (light and UV protection) with chemical UV

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filters. The UV filters can be water or oil soluble such as sulphonic acid derivatives of benzophenones and benzimidazole derivatives of dibenzoylmethane. Benzylidene camphor and their derivatives, derivatives of cinnamic acid and their esters, or esters of salicylic acid.(Col 4,line 43-68). Furthermore, other substances such as vitamins, antioxidants, preservatives, colorants and perfumes also can be combined with the coated metal oxide particle as mentioned.(Col.5, line 1-15).

9. Regarding claims 18 and 21. Schumacher also teaches the sun screening agents, i.e the silica-coated metal oxides as emulsifiers and stabilizers such as photostabilizer and there is no need to add any emulsifier, i.e. "emulsifier free"

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher(US2003/0104198) as applied to claim1 above, and further in view of Ziegler et al.(EP576,188). Schumacher teaches a silica-coated metal oxide as a UV protectant that can be used in cosmetics due to its low structure and are therefore easy to incorporate in cosmetic formulations which are resistant to sedimentation. Ziegler, on the other hand teaches a composition of self-tanning of skin with

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dihydroxacetone and its derivatives. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teaching of Ziegler of a self tanning cream with the teaching of Schumacher of a UV protectant particles to provide a self tanning capability to a UV protectant dermatological formulation for indication of application areas.

12. Claims 1 and 17. are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al (EP 576,188) and further in view of Schumacher. Ziegler teaches a self tanning formula but does coated metal oxide particles. Schumacher teaches a silica coated metal oxide in sun screen lotion comprising coated metal oxide particles which have a low structure and therefore are easy to incorporate in cosmetic formulations which are resistant to sedimentation. It would have been obvious for a person having ordinary skill in the art at the time of the invention to add the particles of Schumacher to the Ziegler composition to provide an added benefit of UV protection to a self tanning formula in addition to sedimentation resistance as demonstrated by Schumacher.

11. Claim 18. is rejected under 35 U.S.C. 103 (a) as being unpatentable over Schumacher as applied to claim 1 above, and further in view of Bicard-Benhamou et al. (PCT/EP04/03090). Schumacher teaches composition of a UV protection silica-coated metal oxide that is suitable for dermatological application, but does not teach a specific photostabiliser. Benhamou teaches a formulation of a photostabiliser that also is suitable for dermatological application. It would have been obvious for a person having

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ordinary skill in the art to add the photostabilizer of Benhamou to the composition of Schumacher in order to stabilize the composition against light exposure for sunscreen material as both references teach dermatological compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLETTE NGUYEN whose telephone number is (571)270-5831. The examiner can normally be reached on Monday-Thursday, 10:00-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Mc Neil can be reached on (571)-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLETTE NGUYEN/
Examiner, Art Unit 4162

/Jennifer McNeil/

Supervisory Patent Examiner, Art Unit 4162